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**IN THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF UTAH, CENTRAL DIVISION**

UNIVERSITY OF UTAH RESEARCH
FOUNDATION, a Utah nonprofit corporation; the
TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA, a Pennsylvania nonprofit
corporation; HSC RESEARCH AND
DEVELOPMENT LIMITED PARTNERSHIP, a
Canadian limited partnership organized under the laws
of the Province of Ontario; ENDORECHERCHE,
INC., a Canadian corporation organized under the laws
of the Province of Quebec; and MYRIAD
GENETICS, INC., a Delaware corporation;

Plaintiffs,

vs.

GENE BY GENE LTD,

Defendant.

**COMPLAINT
DEMAND FOR JURY TRIAL**

Case No. 2:13-cv-00643-EJF

Magistrate Judge Evelyn J. Furse

COMPLAINT FOR PATENT INFRINGEMENT

1. Plaintiffs, University of Utah Research Foundation (“University of Utah”), The Trustees of the University of Pennsylvania (“University of Pennsylvania”), HSC Research and Development Limited Partnership (“Hospital for Sick Children”), Endorecherche, Inc. (“Endorecherche”), and Myriad Genetics, Inc. (“Myriad”), complain against Defendant Gene By Gene, Ltd. (“Defendant”) as follows:

JURISDICTION AND VENUE

2. This civil action for patent infringement arises under the patent laws of the United States, specifically under Title 35 of the United States Code, Sections 271, *et seq.* Subject matter jurisdiction in this Court is founded upon 28 U.S.C. §§ 1331 and 1338(a).

3. This Court has personal jurisdiction over the Defendant because it regularly conducts business in this district and has committed acts in this judicial district which give rise to this action. On information and belief, Defendant sells, offers for sale, and has sold genetic testing products to residents of this jurisdiction. On information and belief, Defendant has attended, advertised, and or presented at conferences and/or meetings held in this jurisdiction in which it sells, offers for sale, has sold, and advertises its genetic testing products. On information and belief, Defendant has business relationships and/or has collaborated with multiple business and/or research entities in this district to which it sells, offers for sale, has sold, and/or advertises its genetic testing products.

4. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and/or 28 U.S.C. § 1400(b).

PARTIES

5. The University of Utah is a Utah nonprofit corporation with an address at 421 Wakara Way, Suite 170, Salt Lake City, Utah 84108. The University of Utah is the owner or co-owner of United States Patent Nos. 5,709,999; 5,747,282; 5,753,441; 5,837,492; and 6,033,857.

6. The University of Pennsylvania is a Pennsylvania nonprofit corporation with an address of 3160 Chestnut Street, Suite 200, Philadelphia, Pennsylvania 19104-6283. The University of Pennsylvania is a co-owner of United States Patent Nos. 6,033,857 and 5,837,492.

7. The Hospital for Sick Children is a Canadian limited partnership organized under the laws of the Province of Ontario, with an address of 555 University Avenue, Toronto, Ontario M5G 1X8, Canada. The Hospital for Sick Children is a co-owner of United States Patent Nos. 6,033,857 and 5,837,492.

8. Endorecherche is Canadian corporation organized under the laws of the Province of Quebec, with a place of business at 2989 De La Promenade, Ste-Foy, Quebec, QC G1W 2J5, Canada. Endorecherche is a co-owner of United States Patent Nos. 6,033,857 and 5,837,492.

9. Myriad is a Delaware corporation, with its principal place of business at 320 Wakara Way, Salt Lake City, Utah 84108. Myriad owns United States Patent Nos. 5,654,155; 5,750,400; 6,951,721; and 7,250,497. Further, Myriad is the exclusive licensee of United States Patent Nos. 5,709,999; 5,747,282; 5,753,441; 5,837,492; and 6,033,857.

10. Plaintiffs are informed and believe, and on that basis allege, that Defendant is a Texas limited partnership that has its principal place of business at 1445 North Loop West, Suite 820, Houston, Texas 77008.

GENERAL ALLEGATIONS

11. Myriad is a molecular diagnostic company that develops and uses proprietary technologies that permit doctors and patients to understand the genetic basis of human disease and the role that genes play in the onset, progression and treatment of disease. Myriad's technologies result in, and guide the development of, new molecular diagnostic products that assess an individual's risk for developing disease, identify a patient's likely response to drug therapy, and assess a patient's risk of disease progression and recurrence.

12. For healthcare providers, Myriad offers an array of genetic tests, prognostic tests and

personalized medicine tests to help healthcare providers assess a patient's increased cancer risk, disease aggressiveness and optimize efficacy of chemotherapy. Myriad's testing products provide healthcare providers with information to help make medical management decisions to reduce cancer risk and help make sure specific treatments are tailored for each individual patient.

13. For patients, Myriad offers tests that provide important clinical information to assist patients and their healthcare providers in assessing cancer risk so the patient can take preventative action to reduce the risk of disease and in making treatment decisions if the patient is diagnosed with cancer. Myriad improves patient care through the development of new products across multiple medical specialties.

14. In the early-to-mid 1990s, Plaintiffs discovered the genetic sequences of the BRCA1 and BRCA2 genes and mutations that increase a woman's risk of developing breast and ovarian cancer. Since that time, Myriad has invested over \$500 million to implement this discovery and create a molecular diagnostic test for hereditary breast and ovarian cancer related to the BRCA1 and BRCA2 genes. Plaintiffs' efforts have revolutionized patient care and provided medical diagnosis and treatment options never thought possible.

15. Defendant offers laboratory services, including clinical diagnostic and genomic services, including testing and analysis of BRCA1 and BRCA2 genes.

16. Defendant, through its DNA Traits division, began offering its BRCA1 and BRCA2 analysis as part of its testing menu on June 13, 2013. Defendant offers stand-alone tests comprising full gene sequencing and analyses for the BRCA 1 and BRCA 2 genes.

FIRST CLAIM FOR RELIEF

(By the University of Utah and Myriad for Infringement of United States Patent No. 5,709,999)

17. Plaintiffs repeat and reallege the allegations set forth in preceding paragraphs 1 through 16, inclusive.

18. United States Patent No. 5,709,999 (the "999 Patent"), was duly and legally issued

by the United States Patent and Trademark Office on January 20, 1998. The University of Utah is the owner and Myriad is the exclusive licensee of the '999 Patent. A true and correct copy of the '999 Patent is attached hereto and incorporated herein by reference as Exhibit 1.

19. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '999 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold BRCA1 and BRCA2 products that infringe at least the following claim of the '999 Patent literally and/or under the doctrine of equivalents: Claim 6.

20. Plaintiffs have been damaged and have suffered irreparable injury due to Defendant's acts of infringement, and will continue to suffer irreparable injury unless Defendant's acts are enjoined.

21. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein. The University of Utah has suffered and will continue to suffer substantial damage in the form of reduced royalty payments by reason of Defendant's acts of patent infringement and the resulting reduction in Myriad's sales revenues. Plaintiffs are entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

22. Defendant has willfully infringed the '999 Patent.

23. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF

(By the University of Utah and Myriad for Infringement of United States Patent No. 5,747,282)

24. Plaintiffs repeat and reallege the allegations set forth in preceding paragraphs 1 through 23, inclusive.

25. United States Patent No. 5,747,282 (the “’282 Patent”), was duly and legally issued by the United States Patent and Trademark Office on May 5, 1998. The University of Utah, along with the Public Health Service, through the National Institutes of Health (“PHS”), are the owners, and Myriad is the exclusive licensee, of the ’282 Patent. A true and correct copy of the ’282 Patent is attached hereto and incorporated herein by reference as Exhibit 2.

26. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the ’282 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold BRCA1 and BRCA2 products that infringe at least the following claims of the ’282 Patent literally and/or under the doctrine of equivalents: Claims 6, 16, and 17.

27. Plaintiffs have been damaged and have suffered irreparable injury due to Defendant’s acts of infringement, and will continue to suffer irreparable injury unless Defendant’s acts are enjoined.

28. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant’s acts of patent infringement as alleged herein. The University of Utah has suffered and will continue to suffer substantial damage in the form of reduced royalty payments by reason of Defendant’s acts of patent infringement and the resulting reduction in Myriad’s sales revenues. Plaintiffs are entitled to recover from Defendant the damages sustained as a result of Defendant’s acts.

29. Defendant has willfully infringed the ’282 Patent.

30. Defendant’s acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

THIRD CLAIM FOR RELIEF

(By the University of Utah and Myriad for Infringement United States Patent No. 5,753,441)

31. Plaintiffs repeat and reallege the allegations set forth in preceding paragraphs 1 through 30, inclusive.

32. United States Patent No. 5,753,441 (the “’441 Patent”), was duly and legally issued by the United States Patent and Trademark Office on May 19, 1998. The University of Utah and PHS are the owners, and Myriad is the exclusive licensee, of the ’441 Patent. A true and correct copy of the ’441 Patent is attached hereto and incorporated herein by reference as Exhibit 3.

33. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the ’441 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold BRCA1 and BRCA2 products that infringe at least the following claims of the ’441 Patent literally and/or under the doctrine of equivalents: Claims 7, 8, 12, 23, and 26.

34. Plaintiffs have been damaged and have suffered irreparable injury due to Defendant’s acts of infringement, and will continue to suffer irreparable injury unless Defendant’s acts are enjoined.

35. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant’s acts of patent infringement as alleged herein. The University of Utah has suffered and will continue to suffer substantial damage in the form of reduced royalty payments by reason of Defendant’s acts of patent infringement and the resulting reduction in Myriad’s sales revenues. Plaintiffs are entitled to recover from Defendant the damages sustained as a result of Defendant’s acts.

36. Defendant has willfully infringed the ’441 Patent.

37. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

FOURTH CLAIM FOR RELIEF

(By the University of Utah, the University of Pennsylvania, the Hospital for Sick Children, Endorecherche, and Myriad for Infringement of United States Patent No. 5,837,492)

38. Plaintiffs repeat and reallege the allegations set forth in preceding paragraphs 1 through 37, inclusive.

39. United States Patent No. 5,837,492 (the "'492 Patent"), was duly and legally issued by the United States Patent and Trademark Office on November 17, 1998. The University of Utah, the University of Pennsylvania, the Hospital for Sick Children, and Endorecherche are the owners, and Myriad is the exclusive licensee, of the '492 Patent. A true and correct copy of the '492 Patent is attached hereto and incorporated herein by reference as Exhibit 4.

40. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '492 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold BRCA1 and BRCA2 products that infringe at least the following claims of the '492 Patent literally and/or under the doctrine of equivalents: Claims 29 and 30.

41. Plaintiffs have been damaged and have suffered irreparable injury due to Defendant's acts of infringement, and will continue to suffer irreparable injury unless Defendant's acts are enjoined.

42. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein. The University of Utah, the University of Pennsylvania, the Hospital for Sick Children, and Endorecherche have suffered and will continue to suffer substantial damage in the

form of reduced royalty payments by reason of Defendant's acts of patent infringement and the resulting reduction in Myriad's sales revenues. Plaintiffs are entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

43. Defendant has willfully infringed the '492 Patent.

44. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

FIFTH CLAIM FOR RELIEF

(By the University of Utah, the University of Pennsylvania, the Hospital for Sick Children, Endorecherche, and Myriad for Infringement of United States Patent No. 6,033,857)

45. Plaintiffs repeat and reallege the allegations set forth in preceding paragraphs 1 through 44, inclusive.

46. United States Patent No. 6,033,857 (the "'857 Patent"), was duly and legally issued by the United States Patent and Trademark Office on March 7, 2000. The University of Utah, the University of Pennsylvania, the Hospital for Sick Children, and Endorecherche are the owners, and Myriad is the exclusive licensee, of the '857 Patent. A true and correct copy of the '857 Patent is attached hereto and incorporated herein by reference as Exhibit 5.

47. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '857 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold BRCA1 and BRCA2 products that infringe at least the following claim of the '857 Patent literally and/or under the doctrine of equivalents: Claim 4.

48. Plaintiffs have been damaged and have suffered irreparable injury due to Defendant's acts of infringement, and will continue to suffer irreparable injury unless Defendant's acts are enjoined.

49. Myriad has suffered and will continue to suffer substantial damage to its business,

including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein. The University of Utah, the University of Pennsylvania, the Hospital for Sick Children, and Endorecherche have suffered and will continue to suffer substantial damage in the form of reduced royalty payments by reason of Defendant's acts of patent infringement and the resulting reduction in Myriad's sales revenues. Plaintiffs are entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

50. Defendant has willfully infringed the '857 Patent.

51. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

SIXTH CLAIM FOR RELIEF

(By Myriad for Infringement of United States Patent No. 5,654,155)

52. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 51, inclusive.

53. United States Patent No. 5,654,155 (the "'155 Patent'"), was duly and legally issued by the United States Patent and Trademark Office on August 5, 1997. Myriad is the owner of the '155 Patent. A true and correct copy of the '155 Patent is attached hereto and incorporated herein by reference as Exhibit 6.

54. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '155 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold BRCA1 and BRCA2 products that infringe at least the following claims of the '155 Patent literally and/or under the doctrine of equivalents: Claims 2, 3, and 4.

55. Myriad has been damaged and has suffered irreparable injury due to Defendant's acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant's acts are

enjoined.

56. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

57. Defendant has willfully infringed the '155 Patent.

58. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

SEVENTH CLAIM FOR RELIEF

(By Myriad for Infringement of United States Patent No. 5,750,400)

59. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 58, inclusive.

60. United States Patent No. 5,750,400 (the "'400 Patent'"), was duly and legally issued by the United States Patent and Trademark Office on May 12, 1998. Myriad is the owner of the '400 Patent. A true and correct copy of the '400 Patent is attached hereto and incorporated herein by reference as Exhibit 7.

61. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '400 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BRCA1 and BRCA2 products that infringe at least the following claims of the '400 Patent literally and/or under the doctrine of equivalents: Claims 2, 3, 4, 5, 6, and 7.

62. Myriad has been damaged and has suffered irreparable injury due to Defendant's acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant's acts are enjoined.

63. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

64. Defendant has willfully infringed the '400 Patent.

65. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

EIGHTH CLAIM FOR RELIEF

(By Myriad for Infringement of United States Patent No. 6,951,721)

66. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 65, inclusive.

67. United States Patent No. 6,951,721 (the "'721 Patent'"), was duly and legally issued by the United States Patent and Trademark Office on October 5, 2005. Myriad is the owner of the '721 Patent. A true and correct copy of the '721 Patent is attached hereto and incorporated herein by reference as Exhibit 8.

68. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '721 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold BRCA1 and BRCA2 products that infringe at least the following claim of the '721 Patent literally and/or under the doctrine of equivalents: Claim 5.

69. Myriad has been damaged and has suffered irreparable injury due to Defendant's acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant's acts are enjoined.

70. Myriad has suffered and will continue to suffer substantial damage to its business,

including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

71. Defendant has willfully infringed the '721 Patent.

72. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

NINTH CLAIM FOR RELIEF

(By Myriad for Infringement of United States Patent No. 7,250,497)

73. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 72, inclusive.

74. United States Patent No. 7,250,497 (the "'497 Patent"), was duly and legally issued by the United States Patent and Trademark Office on July 31, 2007. Myriad is the owner of the '497 Patent. A true and correct copy of the '497 Patent is attached hereto and incorporated herein by reference as Exhibit 9.

75. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '497 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold BRCA1 and BRCA2 products that infringe at least the following claims of the '497 Patent literally and/or under the doctrine of equivalents: Claims 3, 4, 5, 6, 7, 8, 11, 14, 17, 18, and 19.

76. Myriad has been damaged and has suffered irreparable injury due to Defendant's acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant's acts are enjoined.

77. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business

opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

78. Defendant has willfully infringed the '497 Patent.

79. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

DEMAND FOR JURY TRIAL

80. Plaintiffs demand a trial by jury on all matters herein so triable.

RELIEF REQUESTED

WHEREFORE, Plaintiffs pray for Judgment as follows:

a. That Defendant has infringed, contributed to the infringement of, and induced infringement of, literally and/or under the doctrine of equivalents, the asserted claims of the '999, '282, '441, '492, '857, '155, '400, '721, and '497 patents;

b. That Defendant and its subsidiaries, affiliates, parents, successors, assigns, officers, agents, servants, employees, attorneys, and all other persons acting in concert or in participation with it, be temporarily and preliminarily enjoined during the pendency of this action, and permanently enjoined thereafter, from infringing the '999, '282, '441, '492, '857, '155, '400, '721, and '497 patents, and specifically from directly or indirectly making, using, selling, offering for sale, or importing any products or services embodying the inventions of the '999, '282, '441, '492, '857, '155, '400, '721, and '497 patents, including, without limitation, the Defendant's BRCA1 and BRCA2 products, during the life of the claims of the '999, '282, '441, '492, '857, '155, '400, '721, and '497 patents without Plaintiffs' express written authority;

c. That Plaintiffs be awarded all damages attributable to Defendant's infringement of the '999, '282, '441, '492, '857, '155, '400, '721, and '497 patents in an amount according to proof at trial, but not less than a reasonable royalty;

- d. That Defendant be ordered to deliver to Plaintiffs, for destruction at Plaintiffs' option, all products that infringe the '999, '282, '441, '492, '857, '155, '400, '721, and '497 patents;
- e. That Defendant be required to account for all gains, profits, advantages, and unjust enrichment derived from their violations of the law;
- f. That this case be deemed "exceptional" within the meaning of 35 U.S.C. § 285;
- g. That Plaintiffs be awarded their reasonable attorneys' fees incurred in connection with this matter;
- h. That Plaintiffs be awarded enhanced damages and/or costs pursuant to 35 U.S.C. § 285 and/or applicable law;
- i. That Plaintiffs be awarded the costs of suit, and an assessment of interest; and,
- j. That the Court award Plaintiffs such other, further, and different relief as the evidence may require and as the Court deems proper under the circumstances.

DATED this 10th day of July, 2013.

/s/ David G. Mangum

DAVID G. MANGUM

C. KEVIN SPEIRS

KRISTINE EDDE JOHNSON

MICHAEL R. MCCARTHY

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